IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF TENNESSEE
NASHVILLE DIVISION

DANA ZETTLEMOYER., individually and on behalf of all others similarly situated, Plaintiff, v. ALLERGAN, INC. f/k/a INAMED CORPORATION, ALLERGAN USA, INC., and ALLERGAN plc. Defendants.	)	Case No. _____ **JURY DEMAND**

CLASS ACTION COMPLAINT

Plaintiff Dana Zettlemoyer individually and on behalf of all others similarly situated, files this Class Action Complaint against Defendants Allergan plc, Allergan, Inc., and Allergan USA, Inc. ("Defendants" or "Allergan") and allege as follows:

NATURE OF THE ACTION

1. Allergan manufactures and sells BIOCELL saline-filled and silicone-filled breast implants and tissue expanders. Allergan's BIOCELL line of implants are a type of textured breast implants and tissue expanders that were first introduced internationally in the early 1990s and in the United States beginning in 2006.

2. The BIOCELL textured implants were originally developed in the 1980s and early 1990s by McGhan Medical Corporation ("McGhan"), which later became Inamed Corporation ("Inamed"). In 2006, Allergan acquired Inamed.

3. In 2011, the Food and Drug Administration ("FDA") identified a potential link between textured breast implants and a rare form of lymphoma called breast-implant-associated anaplastic large-cell lymphoma, or BIA-ALCL.

4. Following a request from the FDA, on July 24, 2019, Allergan announced it was issuing a worldwide recall of all BIOCELL textured breast implants and tissue expanders. The FDA made its request after receiving reports suggesting that BIOCELL implants and expanders were associated with hundreds of cases of BIA-ALCL around the world. In its notice to the public, the FDA reported receiving 573 cases of BIA-ALCL worldwide, including 33 deaths. The FDA further noted that it had seen "a significant increase in known cases of BIA-ALCL since the agency's last update earlier this year—an increase of 116 new unique cases and 24 deaths." Of the 573 known cases of BIA-ALCL, 481 (or about 84%) were attributed to Allergan products, and of the 33 reported deaths, "12 of the 13 patients for which the manufacturer of the implant is known are confirmed to have an Allergan breast implant[.]" According to the FDA, the risk of BIA-ALCL is six times higher with Allergan's textured implants than textured implants from other manufacturers.

5. BIA-ALCL is not breast cancer but rather a type of non-Hodgkin's lymphoma, a cancer of the immune system. BIA-ALCL typically occurs in the scar tissue surrounding the implant. Left untreated, it will spread to surrounding tissue such as lymph nodes near the breast and may be fatal. BIA-ALCL is typically treated with surgery meant to remove the implant and surrounding scar tissue although some patients will require chemotherapy, radiation therapy, or both.

6. The main symptoms of BIA-ALCL are persistent swelling or enlargement of a patient's breast or surrounding tissue that develops a year or more after surgery (swelling is

common immediately after surgery), lumps in the breast or armpit, pain, rash or redness, hardening of the breast, or changes in the shape or size of the breast.

7. After Allergan's recall, a principal FDA deputy commissioner stated that: "[b]ased on new data, our team concluded that action is necessary at this time to protect the public health" and that "[o]nce the evidence indicated that a specific manufacturer's product appeared to be directly linked to significant patient harm, including death, the FDA took action."

8. The products subject to recall ("recalled BIOCELL products") include Allergan Natrelle Saline-Filled Breast Implants (formerly called McGhan RTV Saline-Filled Mammary Implants), Allergan Natrelle Silicone-Filled Textured Breast Implants (formerly called Inamed Silicone-Filled Breast Implants), Natrelle 410 Highly Cohesive Anatomically Shaped Silicone-Filled Breast Implants, and Allergan tissue expanders for the breast implants that have BIOCELL texturing.[1]

9. In a July 30, 2019 letter to "Allergan Plastic Surgery Customer[s]", Allergan's Senior Vice President, U.S. Medical Aesthetics, Carrie Strom stated that Allergan is creating a "Replacement Warranty" for patients "currently implanted" with BIOCELL textured implants that will provide smooth device replacements. The letter explained that the warranty program will run until July 24, 2021. The letter also said that "Allergan will not be providing surgical fee assistance" to any patients.

10. On August 9, 2019, Allergan sent a letter informing patients, including Plaintiff, that the recall of the BIOCELL products was due to a "higher occurrence of breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) in patients who have, or have had,

[1] The recalled BIOCELL products are listed in Exhibit A.

Allergan BIOCELL textured breast implants." Allergan's "recall" and "Replacement Warranty" therefore have a glaring shortcoming—while it has agreed to provide smooth breast implants to replace the problematic textured breast implants, Allergan has declined to cover the surgical fees patients must incur to remove the recalled BIOCELL products.

11. As a result of Allergan's conduct, including its refusal to pay for the removal of the recalled BIOCELL products, as well as the substantially increased risk of BIA-ALCL, Plaintiff will be forced to expend substantial sums, such as for surgery to remove her implant, medical monitoring, and other medical expenses.

PARTIES

12. Plaintiff Dana Zettlemoyer is a citizen and resident of Davidson County, Tennessee.

13. Defendant Allergan plc is a publicly traded corporation headquartered in Dublin, Ireland. It has administrative headquarters for the United States in New Jersey.

14. Defendant Allergan, Inc., is a wholly-owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey.

15. Defendant Allergan USA, Inc. is a wholly owned subsidiary of Allergan plc and is incorporated under the laws of Delaware, with its principal place of business in New Jersey.

16. At all relevant times, each Defendant acted in all aspects as the agent and alter ego of each other.

JURISDICTION AND VENUE

17. This Court has jurisdiction over the lawsuit under the Class Action Fairness Act, 28 U.S.C. § 1332, because this is a proposed class action in which: (1) there are at least 100 class members; (2) the combined claims of class members exceed $5,000,000, exclusive of

interest, attorneys' fees, and costs, and (3) Plaintiff and Defendants are domiciled in different states.

18. This Court has personal jurisdiction over Defendants because they have sufficient minimum contacts in Tennessee to render the exercise of jurisdiction by this Court proper and fair. Allergan conducts substantial business in Tennessee and within this District, including the marketing and sale of its BIOCELL products.

19. Venue properly lies in this District pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the acts giving rise to Plaintiff's claims occurred in this District and because Defendants are subject to personal jurisdiction within this District.

PLAINTIFF ALLEGATIONS

20. On November 29, 2016, Plaintiff received Natrelle 410 Style 410 FX silicone-filled breast implants included on the list of recalled BIOCELL products as part of reconstructive surgery following her recovery from breast cancer. The surgery was performed in Nashville, Tennessee.

21. On December 24, 2016, Plaintiff had an emergency surgery to remove one of her two implants. That implant was not replaced.

22. Plaintiff would not have had the Natrelle 410 devices implanted had she known prior to the procedure that BIOCELL textured breast implants would subject her to a significantly greater risk of developing BIA-ALCL, as well as the costs associated with removal, medical monitoring, and other fees and procedures to detect and treat BIA-ALCL. Plaintiff experienced severe emotional distress when she learned that she is now exposed to a significantly greater risk of developing BIA-ALCL.

23. Plaintiff plans to have the implant removed and wants Allergan to fully pay for the removal of her implant, but she (understandably) does not wish to have another Allergan product implanted. Allergan has refused to pay for any surgical costs associated with the recall and the greatly increased risk of BIA-ALCL from using its BIOCELL products.

FACTUAL ALLEGATIONS

I. Relevant Background Concerning Breast Implants

24. Breast implants are medical devices that are implanted under the breast tissue or chest muscle to increase breast size or to replace breast tissue that has been removed as a result of cancer or other trauma. Tissue expanders are typically used in breast reconstruction and are a type of inflatable breast implant that stretches the skin and muscle to make room for a more permanent implant in the future.

25. There are two primary types of breast implant products: saline-filled (containing sterile saltwater) and silicone-filled (containing silicone gel). They come in a variety of sizes, have different gel viscosity, and can have either a smooth or textured surface. Every year, approximately 400,000 women in the United States receive breast implants either for cosmetic reasons or for breast reconstruction.

26. First introduced in the 1960s, breast implants began gaining acceptance and popularity in the 1970s. In 1976, Congress passed the Medical Device Amendment to the Federal Food, Drug and Cosmetic Act granting the FDA authority to review and approve new medical devices, including breast implants. Breast implants were initially classified as Class II devices, which required manufacturers to provide assurances that their products would not cause harm to the recipients but did not require them to conduct any formal testing.

27. Public concerns about the safety of breast implants grew during the late 1980s and early 1990s with increasing reports of health complications such as gel bleed and capsular contracture (scar tissues becoming unusually hard and contracting around the implant). At the same time, studies began to warn about the dangers of silicone implants and their link to cancer. In response, the FDA re-classified both saline-filled and silicone-filled breast implants as Class III devices, meaning they posed a potential unreasonable risk of illness or injury. In 1991, the FDA began requiring Premarket Approval Applications ("PMAs") for breast implants.

28. In 1992, the FDA issued a moratorium on the sale of silicone-filled breast implants due to increasing concerns about their safety. At the time, McGhan and Mentor Corporation were the only silicone breast implant manufacturers left in the United States market.

29. During the late 1990s and early 2000s, McGhan (later Inamed) and Mentor began long-term clinical studies for their silicone implants.

30. Allergan's 2006 acquisition of Inamed was at least partly motivated by the fact that while most of the breast implants in the United States at the time were saline implants, the FDA appeared to be on the verge of lifting the moratorium on silicone implants and Inamed was already selling silicone implants outside of the United States.

31. The FDA lifted the moratorium on silicone implants in 2006. Allergan began selling its Inamed Silicone-Filled Breast Implants in the United States shortly thereafter.

II. Breast Implants and BIA-ALCL

32. After health concerns arose during the 1980s and 90s, manufacturers began using surface texturing on breast implants claiming they would reduce the likelihood of common complications such as capsular contracture. Manufacturers rely on different techniques to create

their textured implants. The variations in manufacturing techniques result in differences in porosity, complexity, and the depth of the texturing on the implant's surface. Allergan's BIOCELL implants use a texturing process called "lost-salt" which uses a layer of salt crystals with a thin overcoat of silicone that is then cured in a laminar flow oven. After the surface is cured, the salt on the surface is washed away leaving a pitted surface with random indentations.

33. Reports and studies linking breast implants to BIA-ALCL began to emerge a few years after the FDA's moratorium was lifted in 2006 and in January 2011, the FDA released a report informing the public about a possible association between breast implants and BIA-ALCL. The FDA observed that "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell."

34. While the risk of ALCL is generally believed to be 1:300,000, textured breast implants greatly increase this risk. The FDA recently announced that its studies have shown that the risk of BIA-ALCL in women with textured implants ranges from 1:3,817 and 1:30,000. The American Society of Plastic Surgeons estimates the current risk of BIA-ALCL to be between 1:2,207 and 1:86,029 for women with textured implants. Studies in Europe show similar risks and Australia's Therapeutic Goods Administration ("TGA") has reported the risk is 1:1,000 to 1:10,000.

35. Since the FDA reported a potential link between breast implants and BIA-ALCL, subsequent studies and reports from other international governmental agencies also showed a heightened risk of BIA-ALCL even as Allergan continued to sell the BIOCELL implants. In March 2015, one analysis identified at least 173 cases and the French National Cancer Institute claimed that "[t]here is a clearly established link between the occurrence of this disease and the presence of a breast implant."

36. On May 19, 2016, the World Health Organization designated BIA-ALCL as a form of T-cell lymphoma distinct from other categories of ALCL that can develop following breast implants.

37. In November 2016, the Australian TGA announced that it would convene an expert advisory panel as part of its "ongoing monitoring of the association between breast implants and anaplastic large cell lymphoma."

38. In early 2017, the National Comprehensive Cancer Network established guidelines for diagnosing and treating BIA-ALCL in breast implant patients.

39. On March 21, 2017, the FDA updated its 2011 warning about the link between breast implants and BIA-ALCL. The FDA stated that "[a]t this time, most data suggest that BIA-ALCL occurs more frequently following implantation of breast implants with textured surfaces rather than those with smooth surfaces."

40. A May 2017 global analysis of some forty governmental databases showed 363 cases of BIA-ALCL of which 258 were reported to the FDA.

41. On March 21, 2018, the FDA released another update, noting that it was aware of 414 total cases of BIA-ALCL.

42. On May 9, 2018, the Australian TGA reported a total of 72 cases of ALCL in Australia.

43. In December 2018, Allergan textured breast implants lost their European certification and subsequently were suspended from the European and Brazilian markets.

44. In February 2019, the FDA sent a letter to health care providers across the United States warning them about the link between textured breast implants and BIA-ALCL.

III. Allergan Enters the Breast Implant Market

45. Many of the recalled BIOCELL products were originally designed, tested, and manufactured by McGhan or Innamed beginning in the 1990s. For instance, while the sale of silicone breast implants was prohibited in the United States after 1992, Allergan's Natrelle 410 silicone breast implant was first introduced in Europe in 1993 as the Biodimensional Style 410 implant.

46. McGhan was once a leading manufacturer of silicone products for plastic and reconstructive surgery. In 1986, First American Corporation changed its name to Inamed Corporation. Inamed was a global healthcare products manufacturer and in March 2006, Allergan acquired Inamed and its wholly owned subsidiary, McGhan for approximately $3.2 billion. Allergan also acquired the BIOCELL trademark and assumed the liability risks for its past and present manufacturing of breast implant products. At the time, Inamed was one of the largest breast implant makers in the world and one of the two largest manufacturers in the United States, primarily competing with Mentor Corporation, now part of Johnson & Johnson.

IV. Allergan Tries to Conceal the Risks of the Recalled BIOCELL Products

47. Consumers and physicians depend on the timely and accurate disclosures of problems and health concerns by medical device manufacturers in their decision-making. Since at least 2011, Allergan has known about the connection between its BIOCELL implants and BIA-ALCL but Allergan did not disclose the connection to consumers or the medical community.

48. Since April 1991, the FDA has required breast implant manufacturers to obtain premarket approval for any silicone gel-filled breast implants through the PMA process, which allows the FDA to evaluate the safety and effectiveness of Class III medical devices.

49. As part of the PMA process, a breast implant manufacturer must provide the FDA with a variety of information including known investigations showing whether or not the device is safe and effective, the components and properties of the device, the manufacturing process and methods, and other data relevant for evaluating the safety and effectiveness of the device that is known or should reasonably be known to the manufacturer.

50. In 2000, Inamed began conducting a 10-year study to assess the performance and safety of the McGhan Medical RTV Saline-Filled Breast Implant.

51. In 2006 Allergan began a series of long-term studies for its Inamed Silicone-Filled Breast Implants to assess the clinical performance of the breast implants, including any health complications and connections to neurological diseases, diseases in the connective tissue, and cancer.

52. Under the relevant PMAs, the "[f]ailure to comply with any post-approval requirement constitutes a ground for withdrawal of approval of a PMA." The PMA also provides that it "is a violation of the act" to commercially distribute "a device that is not in compliance with these conditions[.]"

53. Manufacturers selling medical devices in the United States are under continuing obligations to comply with the medical device reporting requirements. For instance, a manufacturer must report to the FDA within 30 calendar days after receiving or becoming aware of information "from any source, that reasonably suggests that a device" "[m]ay have caused or contributed to a death or serious injury" or that a device "[h]as malfunctioned and this device or a similar device . . . would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50(a).

54. Information is "reasonably known" if it can be obtained by contacting "a user facility, importer or other initial reporter;" is information that is in a manufacturer's possession; or is information that "can be obtain[ed] by analysis, testing, or other evaluation of the device." 21 C.F.R. § 803.50(b). Manufacturers must investigate each reported event and evaluate the cause. *Id.*

55. A manufacturer must also provide periodic reports to the FDA including "[u]npublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant" and "[r]eports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant." 21 C.F.R. § 814.84.

56. Accordingly, manufacturers such as Allergan are required to file adverse event reports with the FDA and continue to have the primary responsibility for timely communicating complete and accurate safety information for breast implants. Manufacturers are further obligated to constantly monitor all reasonably available information and clinical experiences.

57. The FDA publishes adverse event reports in a public, searchable database called the Manufacturer and End User Facility Device Experience database or "MAUDE" which is updated monthly.

58. Instead of accurately reporting adverse events individually each time an injury or malfunction occurred, however, Allergan's practice was to "bury evidence of ruptures and other injuries by reporting them as routine events that did not require public disclosure" until 2017. Allergan hid evidence of complications and injuries by filing "Alternative Summary Reports" ("ASR") that bypass MAUDE. ASRs were initially developed to reduce paperwork. The ASR program allows Allergan to report hundreds or thousands of adverse event reports together on

less-detailed quarterly spreadsheets and avoid public disclosure because the reports are generally unavailable to the public. The ASR system is so obscure that a former commissioner, Dr. Robert Califf, stated that he had "never heard anything about it" during his time with the FDA.

59. The ASR program, moreover, was intended to exclude severe or unexpected events or injuries necessitating remedial action, which were still supposed to be reported individually. Experts, however, have been skeptical that the ASRs really did exclude the more serious events. Madris Tomes—a former FDA data analyst—stated his "concern has always been that these reports contain serious injuries . . . ." Recent developments prove that Allergan did in fact bury serious events in non-public ASRs, including a case of possible BIA-ALCL.

60. Further substantiating the fact that severe breast implant events had been buried in ASRs, in 2017, when the FDA began implementing more rigorous reporting requirements, there was a dramatic increase in the number of adverse events related to breast implant injuries—from 200 a year to 4,567 in 2017 and 8,242 in the first half of 2018.

61. The FDA has now acknowledged that, until recently, there was a "transparency issue" with the injury reports it had been accepting. The FDA said the surge in reports reflected the change in its requirements, rather than "a new public health issue."

62. Accurate reporting of adverse events is critical to ensure that the public is adequately and timely notified of potential problems with a medical device. The FDA relies on the reports to monitor the safety of medical devices. The general public, including physicians and patients, also use the MAUDE database to obtain safety information about medical devices. Researchers, including those studying connections between breast implants and cancer and other health issues, also use the MAUDE database in their studies, such as to obtain the number

of reported injuries or deaths. By using ASRs instead of MAUDE, Allergan was able to paint a misleading picture of the number of problems in breast implants to medical professionals and their patients who relied on the public reports, thereby exposing patients to harm.

63. Allergan also did not report adverse events from its required post-market approval studies that would have suggested the recalled BIOCELL products have caused or contributed to deaths or serious bodily injury.

64. As detailed above, after the FDA lifted the moratorium in 2006, Allergan continually received new information showing the connection between its textured breast implants and BIA-ALCL and that the risk associated with its BIOCELL breast implants was significantly greater than its competitors.

65. Allergan failed to comply with the conditions of the PMAs and violated federal law by failing to fulfill its obligations to accurately and promptly report adverse events and continuing to sell the recalled BIOCELL products.

66. Had Allergan complied with its obligations under federal law, the disclosure of the connection between BIOCELL breast implants and BIA-ALCL would have allowed patients including Plaintiff, and her treating physicians to make an informed decision regarding whether to use other implants.

CLASS ALLEGATIONS

67. Plaintiff brings this action on her own behalf, and on behalf of the following class and state subclasses pursuant to Federal Rules of Civil Procedure 23(a), 23(b)(2), 23(b)(3), and/or (c)(4):

Nationwide Class: All individuals in the United States who implanted BIOCELL© saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA.

Tennessee Subclass: All individuals who implanted BIOCELL© saline-filled or silicone-filled breast implants or tissue expanders that have been recalled by the FDA while those individuals resided in Tennessee.

68. Excluded from the class are Defendants, their parents, subsidiaries, affiliates, officers and directors, any entity in which Defendants have a controlling interest, all class members who timely elect to be excluded, governmental entities, and all judges assigned to hear any aspect of this litigation, as well as their immediate family members. Plaintiff reserves the right to modify, change, or expand the class definition based on facts learned through discovery and further investigation.

69. Numerosity: The members of the class are so numerous that joinder is impractical. The class includes at least thousands of individuals.

70. Typicality: Plaintiff's claims are typical of the claims of the class in that Plaintiff, like all class members, were implanted with recalled BIOCELL products and faced an increased risk of BIA-ALCL.

71. Adequacy: Plaintiff will fairly and adequately protect the interests of the class. Plaintiff has no interests adverse to the interests of any other class member and is committed to vigorously prosecuting this case. Plaintiff has retained competent counsel experienced in the prosecution of complex class actions involving defective products.

72. Commonality and Predominance: There are questions of law and fact common to the class, and the common questions predominate over any questions affecting only individual class members. Among the questions common to the class are:

a. Whether the recalled BIOCELL products significantly increase the risk of developing BIA-ALCL;

b. Whether Allergan knew or should have known that the recalled BIOCELL products significantly increase the risk of developing BIA-ALCL;

c. Whether Allergan was negligent in selling BIOCELL recalled products;

d. Whether Allergan failed to warn consumers regarding the risks of the recalled BIOCELL products;

e. Whether Allergan violated federal standards and requirements for the marketing, warning, and reporting of the recalled BIOCELL products;

f. Whether Allergan breached implied warranties connected with the recalled BIOCELL products;

g. Whether Allergan was unjustly enriched by the sale of the recalled BIOCELL products;

h. Whether Plaintiff and class members are entitled to equitable relief, including injunctive relief; and

i. Whether Plaintiff and class members are entitled to damages or other monetary relief, and if so, in what amount.

73. Superiority: A class action is superior to all other methods available for the fair and efficient adjudication of this controversy. Because the amount of each individual class member's claim is small relative to the complexity of the litigation, and given Allergan's

financial resources, no class member would be likely to pursue legal redress individually for the violations detailed herein. A class action would also streamline the determination of common claims or issues in this case. Conversely, individual suits would create the potential for inconsistent or contradictory rulings. By contrast, a class action presents fewer management difficulties, allows claims to be heard which would otherwise go unheard, and allows comprehensive supervision by a single court.

74. Injunctive Relief: Class certification is also appropriate under Rule 23(b)(2) because Allergan acted and refused to act on grounds generally applicable to the class, making appropriate final injunctive relief with respect to the class as a whole.

CLAIMS FOR RELIEF

FIRST CAUSE OF ACTION

Strict Liability—Failure to Warn

75. Plaintiff incorporates the above allegations by reference.

76. Allergan manufactured, distributed, and/or sold the BIOCELL breast implants that were implanted in Plaintiff.

77. Allergan had a duty to warn Plaintiff and her physicians about the dangers of the recalled BIOCELL products which it knew, or in the exercise of ordinary care, should have known, at the time the recalled BIOCELL products left Allergan's control.

78. The BIOCELL breast implants had potential risks that were known or knowable in light of the scientific and medical knowledge that was generally accepted in the scientific and medical community at the time of the manufacture, distribution, or sale of the implant.

79. Allergan failed to warn Plaintiff and her physicians about the serious risk of using its recalled BIOCELL products, including the greatly increased risk of BIA-ALCL. At

the time Plaintiff received her implants, Allergan was aware of the clear causal connection between its BIOCELL breast implants but did not disclose this information or warn of the significantly greater risk of BIA-ALCL associated with its implants. Allergan obtained this knowledge from performing extensive decades-long clinical studies, reviewing scientific studies and literature, FDA communications, government reports, and from complaints from consumers, among other sources. Rather than disclose the truth, Allergan, in violation of federal law, attempted to conceal the true facts by not reporting all adverse events to the FDA and by filing ASRs to avoid public reporting on MAUDE.

80. Allergan also failed to warn Plaintiff and the public by not submitting accurate adverse event reports that patients and physicians rely on to make informed decisions about selecting the type of breast implants.

81. The recalled BIOCELL products were defective and unreasonably dangerous when they left Allergan's possession because they did not contain adequate warnings, including the greatly increased risk of developing BIA-ALCL. In addition, the recalled BIOCELL products were defective and unreasonably dangerous when they left Allergan's possession because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer or seller would not put such a dangerous product on the market.

82. The potential risks presented a substantial danger to Plaintiff and ordinary consumers when used or misused in an intended or reasonably foreseeable way.

83. Plaintiff and ordinary consumers would have not recognized the potential for risks.

84. Allergan failed to adequately warn or instruct concerning the potential risks of recalled BIOCELL products.

85. It was foreseeable to Allergan that failure to adequately warn about the risks of its recalled BIOCELL products would cause irreparable harm to those who had the products implanted in their bodies, including the types of emotional distress suffered by Plaintiff.

86. As a result of Allergan's failures to adequately warn, Plaintiff was harmed as described herein including physical pain and emotional distress. The lack of sufficient warnings was a substantial factor in causing Plaintiff's harm. If Plaintiff and her physicians had been provided with the appropriate warnings regarding the causal connection between BIOCELL implants and BIA-ALCL, they would have been able to make an informed decision about using an alternative product that did not present such a high risk of BIA-ALCL.

87. Allergan's breach of its duty to warn has caused Plaintiff damages including surgical costs of removal of the products, ongoing medical monitoring, and other medical expenses.

SECOND CAUSE OF ACTION

Negligence

88. Plaintiff incorporates the above allegations by reference.

89. Allergan has a continuing duty to monitor the recalled BIOCELL products to discover and report to the FDA any complaints about product performance and safety. Allergan also has a continuing duty to provide warnings and instructions regarding potential safety hazards associated with the use of its products.

90. Allergan breached these duties by failing to provide timely and adequate reports regarding the safety hazards associated with the recalled BIOCELL products, including the

close causal connection to BIA-ALCL. Through numerous adverse reports, consumer complaints, scientific research and literature, internal clinical research, and communications from the FDA and international governmental organizations that Allergan monitored, Allergan was aware of the clear connection between the recalled BIOCELL products and BIA-ALCL, and that its textured breast implants posed a significantly greater risk than competing textured breast implants.

91. Although Allergan knew or should have known that the recalled BIOCELL products posed a serious risk of bodily harm to consumers, Allergan continued to manufacture and market them to consumers and failed to comply with applicable FDA reporting and monitoring requirements.

92. Had Allergan properly and timely reported the adverse events to the FDA as required under federal law, material information regarding the true risk of the recalled BIOCELL products—including the substantially greater risk of developing BIA-ALCL—would have reached Plaintiff and her treating medical professionals in time to avoid her injuries.

93. Allergan knew or should have known that consumers such as Plaintiff would foreseeably suffer injury as a result of its failure to exercise ordinary care and comply with FDA reporting and monitoring requirements, including emotional distress.

94. As a direct result of Allergan's breach of duty, Plaintiff has suffered harm in an amount to be determined at trial, including severe emotional distress.

THIRD CAUSE OF ACTION

Negligent Recall

95. On July 24, 2019, the FDA requested that Allergan recall its BIOCELL products in the United States. That same day, Allergan voluntarily issued a worldwide recall of BIOCELL products.

96. In issuing a voluntary recall, Allergan assumed duties to Plaintiff to exercise reasonable care in issuing and implementing the recall.

97. Allergan breached its duties by failing to adequately warn Plaintiff of the dangers associated with the use of the recalled BIOCELL products and by refusing to pay for the surgical removal of Plaintiff's implant notwithstanding the clear connection between the recalled BIOCELL products and BIA-ALCL and the continuing risk the implant poses to Plaintiff's health.

98. As a direct result of Allergan's breach of duty, Plaintiff has suffered harm in an amount to be determined at trial.

FOURTH CAUSE OF ACTION

Breach of the Implied Warranty of Merchantability

99. Plaintiff incorporates the above allegations by reference.

100. By operations of law, Allergan—as manufacturer of the recalled BIOCELL products and as the provider of the Limited Warranty—impliedly warranted to Plaintiff that the implants she was receiving were of merchantable quality and safe for their ordinary and intended use in the human body as an aesthetic breast enhancement.

101. The recalled BIOCELL products were defective and unreasonably dangerous when they left Allergan's possession because they did not contain adequate warnings, including the greatly increased risk of developing BIA-ALCL. In addition, the recalled BIOCELL products were defective and unreasonably dangerous when they left Allergan's possession

because they were dangerous to an extent beyond that which would be contemplated by an ordinary consumer—the risk of developing BIA-ALCL was at least six times greater than competing products—and because a reasonably prudent manufacturer or seller would not put such a dangerous product on the market.

102. Allergan breached the implied warranty of merchantability in connection with the sale and distribution of the recalled BIOCELL products. At the point of sale, the recalled BIOCELL products —while appearing normal—contained latent flaws rendering them unsuitable and unsafe for use in the human body.

103. Had Plaintiff known the recalled BIOCELL products are unsafe for use in the human body, she would not have had them implanted in her body.

104. Allergan has refused to provide appropriate warranty relief, as it will not provide surgical fee assistance to patients notwithstanding the substantially increased risk of developing BIA-ALCL. Plaintiff reasonably expected that her implants would not present a substantial risk of bodily harm at the time of their purchases.

105. As a direct and proximate result of Allergan's' breach of the implied warranty of merchantability, Plaintiff has sustained damages in an amount to be determined at trial.

FIFTH CAUSE OF ACTION

Medical Monitoring

106. Plaintiff incorporates the above allegations by reference.

107. As a result of exposure to the recalled BIOCELL products, the need for future monitoring is reasonably certain. Allergan's textured implants significantly increase the risk of BIA-ALCL.

108. Medical monitoring is therefore reasonable in order to properly diagnose the symptoms of BIA-ALCL particularly as it can become fatal when not treated in a timely manner.

109. Plaintiff is therefore entitled to have Allergan pay for the costs of ongoing medical monitoring.

SIXTH CAUSE OF ACTION

Unjust Enrichment

110. Plaintiff incorporates the above allegations by reference.

111. Allergan has been unjustly enriched by benefitting from the sale of the recalled BIOCELL products when it knew that the products greatly increase the risk of developing BIA-ALCL.

112. Plaintiff conferred an economic benefit upon Allergan when she had the recalled BIOCELL products implanted. Plaintiff would not have chosen the recalled BIOCELL products or had them implanted had she known that she would be exposed to a substantially increased risk of developing BIA-ALCL.

113. Allergan has appreciated and accepted the benefit conferred by Plaintiff even though it knew of the connection between the recalled BIOCELL products and BIA-ALCL.

114. Under these circumstances, it would be unjust and inequitable for Allergan to retain the benefit it has received at the expense of Plaintiff.

115. As a result of the foregoing, Plaintiff has suffered damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff requests, individually and on behalf of the Class, that this Court:

A. Certify the class under Fed. R. Civ. P. 23(a), (b)(1), (b)(2), (b)(3), and/or (c)(4), as appropriate; appoint Plaintiff as representative of the class; and appoint the undersigned counsel as class counsel;

B. Award Plaintiff compensatory, restitutionary, rescissory, general, consequential, punitive and/or exemplary damages in an amount to be determined at trial;

C. Award prejudgment interest as permitted by law;

D. Enter an injunction against Allergan and its officers, agents, successors, employees, representatives, assigns, and any and all persons acting in concert with them, to require them to implement a medical monitoring program for Plaintiff and class members;

E. Retain jurisdiction over this action to ensure Allergan complies with such a decree;

F. Enter other appropriate equitable relief;

G. Award reasonable attorneys' fees and costs, as provided for by law; and

H. Grant such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff requests a trial by jury of all issues triable as of right.

Dated: September 30, 2019

Respectfully submitted,

By: /s/Jerry E. Martin
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**Pro Hac Vice* Admission Anticipated